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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,584

08/25/2003

Arthur M. Krieg

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/649,584	Applicant(s) KRIEG ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/8/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,87 and 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to an amendment filed 7/9/08. Claims 1, 2, 87 and 88 are pending in this action.

Applicants' arguments concerning the rejection under 35 USC 112, first paragraph have been considered and are persuasive. However, upon reconsideration new grounds of rejection have been made as set forth below.

Information Disclosure Statement

An IDS filed 12/10/07 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action. Documents listed that have not been located have not been considered and have been crossed out. If applicants want the items listed in the IDS filed 12/12/03 to be considered, new copies of the articles should be sent, accompanied by a new Form 1449.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 87 are rejected under 35 U.S.C. 102(e) as being anticipated by Hutcherson et al (US 5,723,335; see entire document). **This is a new rejection.**

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Hutcherson et al (US 5,723,335; see entire document).

Hutcherson et al teach methods of stimulating an immune response using oligonucleotide and oligonucleotide analogs (see e.g. abstract). These oligonucleotides have CG motifs (see e.g. SEQ ID NO:1, 2 and 3). These oligonucleotides are non-palindrome. Immunostimulatory responses including increase in B-cell (see e.g. example 10).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 2, 87 and 88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-43, 46-52, 56-61 and 91-101 of copending Application No. 11/296,644. **These rejections are maintained from the rejection mailed 1/9/08 and restated below.**

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims as being unpatentable over claims 37-43, 46-52, 56-61 and 91-101 of copending Application No. 11/296,644. That is, the cited claims of U.S. Application No. 11/296,644 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, both applications recite a method of inducing an immune response in a subject with an immune deficiency associated with a viral infection using unmethylated CpG nucleic acids.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the U.S. Application No. 11/296,644, then two

different assignees would hold a patent to the claimed invention of U.S. Application No. 11/296,644, and thus improperly there would be possible harassment by multiple assignees.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-56 of copending Application No. 10/788,191 and claim 1, 2 and 88 over claims 37-65 of copending Application No. 11/067,516 and claims 1 and 2 over claims 19-33 of copending application 10/987146 and claims 1, 2 and 88 over claims 42-68 of copending application 10/382822. **These rejections are maintained from the rejection mailed 1/9/08 and restated below.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite methods of administering an unmethylated CpG to a subject associated with HIV infection. The instant claims recite that administration results in a boost in the immune system, while the copending applications recite that the method treats the HIV infection. It would have been obvious to one of ordinary skill at the time of the invention was made to boost the immune system of the subject coordinate with the administration because the instant invention teaches that it is within the ordinary skill of the art to administer the CpG to subjects with HIV immune deficiency and because the copending applications teach that immune boost is critical to treatment of HIV infection. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding a patent from 10/788,191, 11/067,516, 10/987146, 10/382822 then several different assignees would hold a patent to the claimed invention of the copending applications, and thus improperly there would be possible harassment by multiple assignees.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 45 of copending application 11/361313 and claims 37, 39-45 and 47-61 of copending application 10/788199. **These are new rejections.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite methods of administering an unmethylated CpG to a subject associated with infection. The instant claims recite that administration results in a boost in the immune system in a subject with HIV disease, while the copending applications recite that a method of administering an oligonucleotide to a subject with an infectious disease or infection. It would have been obvious to one of ordinary skill at the time of the invention was made to boost the immune system of the subject coordinate with the administration because the instant invention teaches that it is within the ordinary skill of the art to administer the CpG to subjects with HIV immune deficiency and because the copending application teaches that an infection leading to an infectious disease to be treated is HIV. Based upon the teachings of the

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cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding a patent from 11/361313 then several different assignees would hold a patent to the claimed invention of the copending applications, and thus improperly there would be possible harassment by multiple assignees.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument

It is acknowledged that applicants' will address the provisional obviousness double patenting rejections upon indication of allowable subject matter. However, until the recited claims are patented or a terminal disclaimer is filed, the claims remain rejected.

Conclusion

No Claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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Primary Examiner, Art Unit 1633